

NAVAL POSTGRADUATE SCHOOL

MONTEREY, CALIFORNIA

THESIS

BIOWATCH: CASE FOR CHANGE OF TRADITIONAL LEADERSHIP TO IMPROVE PERFORMANCE

by

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September 2009

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REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instruction, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704–0188) Washington DC 20503.

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE September 2009	3. RE	EPORT TYPE AND DATES COVERED Master's Thesis	
4. TITLE AND SUBTITLE BioWatch: Case for Change of Traditional Leadership to Improve Performance6. AUTHOR(S) Nancy S. Bush			5. FUNDING NUMBERS	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Naval Postgraduate School Monterey, CA 93943–5000		8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING /MONITORING AGENCY NAME(S) AND ADDRESS(ES) N/A		10. SPONSORING/MONITORING AGENCY REPORT NUMBER		

11. SUPPLEMENTARY NOTES The views expressed in this thesis are those of the author and do not reflect the official policy or position of the Department of Defense or the U.S. Government.

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (maximum 200 words)

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This thesis explores the current assigned leadership of the BioWatch Program primarily at the state and local levels. By using the experiences of the Missouri BioWatch Program in St. Louis, a shared leadership is suggested between the state health department and the state EPA to maximize efforts and related to the BioWatch Program by use of a memorandum of agreement.

14. SUBJECT TERMS BioWatch Public Health Preparedness	15. NUMBER OF PAGES 83 16. PRICE CODE		
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UU

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2–89) Prescribed by ANSI Std. 239–18

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BIOWATCH: CASE FOR CHANGE OF TRADITIONAL LEADERSHIP TO IMPROVE PERFORMANCE

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Submitted in partial fulfillment of the requirements for the degree of

MASTER OF ARTS IN SECURITY STUDIES (HOMELAND SECURITY AND DEFENSE)

from the

NAVAL POSTGRADUATE SCHOOL September 2009

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ABSTRACT

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This thesis explores the current assigned leadership of the BioWatch Program primarily at the state and local levels. By using the experiences of the Missouri BioWatch Program in St. Louis, a shared leadership is suggested between the state health department and the state EPA to maximize efforts and related to the BioWatch Program by use of a memorandum of agreement.

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ACKNOWLEDGMENTS

I would like to acknowledge my thesis advisor, Anke Richter, and second reader, Kathleen Wojciehowski, for their guidance and encouragement throughout this process. Additionally, I would like to recognize my mentor and colleague, Pamela Rice Walker, Director of the St. Louis City Health Department. Pam has always encouraged me and has always believed in me. I appreciate her expertise and assistance with this project.

I. INTRODUCTION

A. DESCRIPTION OF THE PROBLEM

Since the terrorist attacks on the U.S. in September 2001 and the anthrax letters that closely followed, there is considerable focus on the threat of biological terrorism in the civilian United States. Biological terrorism is not a new concept; however, military leaders throughout history considered infectious disease pathogens as weapons in military campaigns. Western powers, including the U.S., Great Britain, Canada, and the former Soviet Union had biological weapons research programs for both offensive and defensive purposes. To have a successful biological weapons program, the delivery method must be efficient and affect as many of the targeted population as possible. Therefore, in a military setting, biological warfare agents are most likely to be delivered by aerosol dispersion in order to optimize the impact on the targeted population. In response, to protect its own population or military troops, the U.S. developed air-monitoring technologies to detect such attacks. An air monitoring system, Program BioWatch, was introduced in the civilian U.S. in 2003 to detect an intentional release of a biological agent in a major metropolitan area. The program was introduced to the state and local partners through the U.S. Environmental Protection Agency (EPA) very quickly and with little guidance on how to coordinate the program and expectations.

In February 2004, the report entitled "EPA's Homeland Security Role to Protect Air for Terrorist Threats needs to be Better Defined," states the EPA plays a supporting role in the BioWatch Program by facilitating the program's air sampling. It is noted in the report that EPA officials lack clearly defined roles and responsibilities needed to effectively perform their duties in meeting the challenges EPA faces in protecting the nation against the threat of terrorism.¹ The report also states, "Our report does not claim that EPA's Office of Homeland Security does not know its responsibilities; rather, we believe this office is not fulfilling its responsibilities as delegated by the EPA

¹ Office of the Inspector General Evaluation Report, *EPA's Homeland Security Role to Protect Air from Terrorist Threats Needs to be Better Defined*, Report no. 2004–M–000005, February 20, 2004.

administrator."² The Office of Inspector General followed up this report with another one in March 2005, "EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program." This report claims that the EPA did not ensure that the BioWatch Network was deployed and maintained adequately as well as that the agency was not prepared to assist with consequence management plans.³

The U.S. EPA is not the only federal program that is not receiving high marks for its management of the BioWatch Program. The 2005 Ready or Not? Protecting the Public's Health From Disease, Disasters, and Bioterrism, published by Robert Wood Johnson Foundation's, Trust for America's Health, noted a grade of "D" for "Coordination among federal agencies, the establishment of measurable goals and directions, BioWatch, and the federal health response to Hurricane Katrina" in its key findings.⁴ The 2008 Ready or Not? report continued to point out problems related to the BioWatch Program directly related to the laboratory component and include the following.

- The lack of contractual relationship between DHS and public health laboratories
- Uncompensated laboratory costs
- Unclear rules for the management and oversight of BioWatch contract employees by state public health lab employees
- Gaps in performance data necessary for state and local labs to assess BioWatch responses
- Security clearance concerns⁵

The St. Louis, Missouri BioWatch Program, as many as other BioWatch Programs, is still working through complicated issues and "growing pains" related to strategies and policies at the state and local levels. The strategies and policies are

² Office of the Inspector General Evaluation Report, *EPA's Homeland Security Role to Protect Air from Terrorist Threats Needs to be Better Defined*, 9.

³ Office of the Inspector General Evaluation Report, *EPA Needs to Fulfill Its Designated Responsibilities to Ensure an Effective BioWatch Program*, Report no. 2005–P–00012, March 23, 2005.

⁴ Trust for America's Health Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, December 12, 2005, 2.

⁵ Ibid., 62.

continuously being updated and implemented in order to make the program more effective. This paper explores a solution that will enhance the BioWatch Program's effectiveness at the state and local levels by ensuring a solid relationship between state agencies and the local agencies that are responsible for the program. This solution may also be applied to other BioWatch Programs, especially those programs that are multi-departmental at the state and local levels, which make decisions and planning more challenging than those programs that are in a single governmental department.

Currently, the BioWatch Program is administered by the U.S. Department of Homeland Security (DHS) on the federal level. DHS administers the program through the state equivalent to the U.S. EPA and directly to the state EPAs. The state agencies in turn work with and enter into a contractual relationships with the local public health agency(ies), which collects filters on a daily basis. The procedures do not include the state health department, which is the traditional partner with the local public health agencies and is the provider of support for local public health programs, including preparedness for emergencies such as bioterrorism. In addition, the procedures and system do not provide administrative accountability for the local public health agencies and their role in the BioWatch Program. Local public health officials do not have formal or consistent guidance from the federal or state BioWatch Program regarding reporting BioWatch filter positives to state public health officials. Figure 1 is a chart that demonstrates the flow and relationships of the key players of the BioWatch Program. A state agency that primarily regulates pollutants and harmful agents, such as industrial emissions, asbestos, and mercury has been placed in a position where it is required to provide administrative support and leadership for a profession and organizations with which it has no traditional relationship or influence. Although the state and federal EPA departments play a key role in BioWatch, the lack of understanding between the professions causes miscommunication and deters better management and promotion of the BioWatch Program.

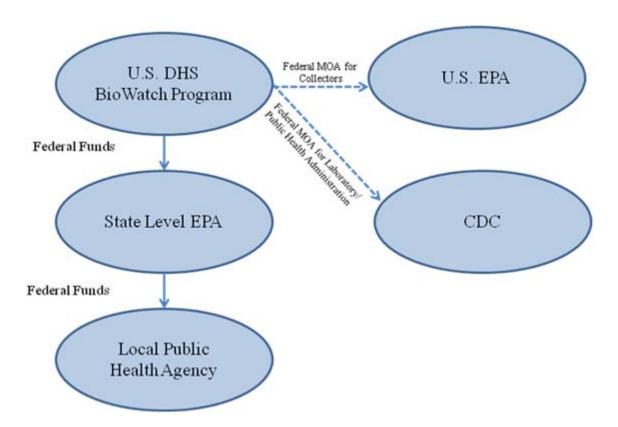


Figure 1. BioWatch Program Administration Cycle: The DHS BioWatch Program directly funds the state EPA and works with the U.S. EPA to coordinate at the state level. The state EPA provides dollars to the local public health agencies leaving out the state health department as an appropriate administrator and a standard public health partner.

The lines of responsibility and communication are fuzzy at best and in some cases are difficult to determine where they are and who has responsibility for significant management of the program outside the laboratory and filter replacement and transport aspects of the program. It is unclear what is supposed to happen with the information and who is supposed to lead the response in the case a situation is detected. Currently, the U.S. Department of Homeland Security administers the BioWatch Program with assistance from CDC and the U.S. EPA. Dollars flow directly to the states' environmental agencies to the local public health agencies. There are no traditional or economic ties between these organizations at the local level. The inconsistent and

confusing manner that the BioWatch Program has taken will continue to cause low "grades" for all involved, which translates to uncertainty to the general public when a positive is detected and instruction is provided.

The BioWatch Network relies on partnerships. This collaboration includes every facet of BioWatch, from placing of air monitors by the federal EPA, collection of filters by the local public health agencies, testing and identification of an agent by the local or state laboratory, to consequence management by all the state, local and federal public health, EPA, law enforcement, and emergency management agencies. The competence of an effective system relies heavily on the organizations at the state and local levels that understand the biological agents and will provide epidemiological investigation support, coordinate mass distribution and dispensing of medications, and that can successfully prepare for, mitigate, respond to and recover from a massive outbreak—specifically public health.

From the beginning of the BioWatch Program, there were signs of limited involvement from the public health sector and the BioWatch Program management at the federal level did not encourage or mandate public health's seat at the table. Because of the limited involvement of public health at the beginning, it affected the EPAs ability to make local public health agencies accountable for administration oversight, strategic planning, consequence management and reporting efforts. This is primarily because they did not traditionally work with public health entities and did not have the authority to require planning efforts outside of the laboratory and collection cycle.

Another aspect that caused the inability to hold local agencies accountable is tied to many aspects of how the BioWatch Program was presented initially and how the program is financially administered and continues to be today from DHS through the state EPA departments. In January 2003, the state level EPA departments of the states that "may" have a BioWatch city participated in a conference call hosted by the Environmental Council of the States, Appendix A is a letter from the Missouri Department of Natural Resources to the states Homeland Security Advisor dated January 30, 2003 discussing the call. The call outlined how the program would "unfold" within 60 days of the call, which included placing monitor in 20 major cities in the nation;

collection of the filters would be done daily and transported to a laboratory within the National Response Laboratory Network; funding for the BioWatch program would be distributed to the states through a granting process that would cover equipment purchases, installation of monitoring equipment, and maintenance; and laboratory funding would come from a separate source. The state EPA departments were also instructed to coordinate with state homeland security advisors and health departments after the call; however, those entities were not invited to the initial planning calls or meeting regarding the program and were never given a chance to contribute to the planning and rolling out of the program.⁶

It can be inferred from this letter that key partners were not invited to the initial call to discuss the BioWatch Program, and, therefore, key partners were excluded from critical information from the beginning. The letter also outlines the grant source for the BioWatch program and indicates that it will be used for equipment and maintenance. There is no mention of funding for consequence management and administration of the public health aspect of the program leaving out critical components. Components that need consideration from the BioWatch Program administration include complicated planning pieces that include a wide variety of partners, e.g., law enforcement and courier services, training, annual exercises, and monitoring of the day-to-day aspects of the program. At no point is it noted that the Environmental Council of the States or the U.S. EPA discuss funding for above administration or training related to the program. The funding stream continues today for supplies and replacement equipment only.⁷

If the BioWatch Program is to be most effective the strategies and polices related to administration and its implementation must be clearly defined and the public health responsibilities shifted to the state public health department so that effective administration and consequence management can be achieved. The focus of this research is to explore how to accomplish the leadership change.

⁶ Letter from Stephen Mahfood, Director of Missouri Department of Natural Resources to Colonel Tim Daniels, Director of Missouri Office of Homeland Security, January 30, 2003. Letter in private papers of Nancy Bush.

⁷ State of Missouri, Missouri State Auditor's Office, *Single Audit Year Ended June 30*, 2007, Report no. 208–17, March 2008, 25.

B. BACKGROUND

The BioWatch Program is new in the civilian arena, and, therefore, the strategies, policies, and technology surrounding the program are still in development and being tested by real events and positives detected from filters collected daily from the field. Since 2003, there have been new guidelines for laboratories and the BioWatch Program has been tested repeatedly, and there has never been a false positive within the system reported through July 2008.⁸ Goals have been defined for the program by the federal government and include the following:

- Provide early warning of a biological attack by quickly identifying the bio-agent, which will minimize casualties in an effected area;
- Assist in establishing forensic evidence on the source, nature, and extent
 of biological attack to assist law enforcement officials in identifying the
 perpetrators; and
- Determine a preliminary spatial distribution of biological contamination, including what populations may have been exposed.⁹

In order for the BioWatch Program to function properly on the federal level operations and agreements were made among the major players of the program. The Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC), a Department of Health and Human Services (HHS) agency were to coordinate and manage their respective responsibilities for the BioWatch Program through a Memorandum of Agreement (MOA) and interagency agreements, which were crafted and signed in 2004. The MOA, Appendix B, requires the following of the EPA:

- Establishing, deploying, operating, and maintaining a network of collectors in BioWatch cities;
- Establishing, operating, and maintaining a filter collection process for such a network;

⁸ House Committee on Homeland Security, Emerging Threats, Cybersecurity, Science and Technology Subcommittee, *One Year Later-Implementing the Biosurveillance Requirements of the 9/11 Act*, Joint Statement of Robert Hooks, Eric Myers, and Jeffrey Stiefel, July 16, 2008, http://homeland.house.gov/Hearings/index.asp?ID=155 (accessed August 8, 2009), 7.

⁹ Office of Inspector General, Homeland Security, *DHS' Management of the BioWatch Program*, OIG-07–22, January 2007, 2.

- Coordinating the monitoring activities of the network with state and local environmental monitoring agencies; and
- Coordinating activities with CDC.¹⁰

For the purposes of this paper, the third and fourth dot points are most critical. The EPA is expected to work and maintain relationships with state and local environmental agencies and coordinate with the CDC on the federal level. According to the MOA, all entities are to be responsible to each other and provide information and reports on a regular basis. However, the U.S. EPA and its partners were not following the MOA and reports were not submitted as outlined.¹¹ The lack of communication between the agencies must have resulted in more confusion at the federal level, which was passed on to the state and local levels regarding BioWatch.

The MOA goes on to require the CDC and its Laboratory Response Network (LRN) to provide technical expertise and services to the BioWatch Program including:

- Providing laboratory analysis services;
- Developing and implementing specific protocols for each laboratory that
 makes up the LRN and its designated as a laboratory responsible for
 BioWatch's filter testing;
- Coordinating activities with the EPA;
- Provide leadership and technical assistance to state and local health department regarding the management of public health emergencies resulting from BioWatch's detection of biological pathogens; and
- Use funding only for specific items related to the BioWatch Program activities that are outlined–Materials, supplies, and personnel related to BioWatch's laboratory staffing, diagnostic hardware, critical and specialty reagents, training, testing travel directly related to the BioWatch Program laboratory support and laboratory personnel evaluation.¹²

The responsibilities outlined for the CDC in the MOA primarily address the LRN and funding related to the LRN. The MOA also mentions coordination and support for the state and local public health departments; however, does not provide funding for

¹⁰ Office of Inspector General, Homeland Security, *DHS' Management of the BioWatch Program*, 2.

¹¹ Ibid., 6.

¹² Ibid., 18.

administrative endeavors for public health addressed earlier and does not provide language for a strong leadership role for state health departments for needed public health oversight of the program.

C. THESIS STRUCTURE

This thesis is organized into four chapters to address a policy change in leadership or policy change from state EPA department/program to the state public health department/program and how should that change occur. Chapter I introduces the problem, background of the BioWatch program, and a review of literature used in development of the thesis. Chapter II outlines cases that emphasize the benefits of the BioWatch Program and demonstrates the necessity of the primary involvement of public health in leading policy for the program. In this chapter, the primary makeup of attendees to BioWatch Program meetings is compared to support the argument of public health's leadership role in the program. Chapter III reviews possibilities for migration from the state EPA departments/programs taking the lead in administration of the BioWatch Program to the state public health department taking on the leadership role for training, education, and monitoring of the program. Chapter IV addresses implementation hurdles, policy implications, and possible further research into solutions for the BioWatch Program.

D. REVIEW OF LITERATURE

The author examined both governmental documents, such as after action reports provided by BioWatch cities that have experienced a positive sample and news articles as foundations for this research. Many of the documents were deemed "For Official Use Only" and are not available for inclusion into this paper. This hurdle does impact the strength of the argument presented in the thesis, which is discussed at more length in the conclusion.

The general description of the BioWatch Program is available in popular news articles as well as governmental documents. The January 22, 2003 article, "Nationwide Monitoring System Planned for Detecting BioTerror Attack," by the Associated Press, ¹³ "BioWarfare Monitors Are Deployed in U.S.," in the January 23, 2003 *Washington Post*, ¹⁴ and the *Houston Chronicle* article, "Government Touts Germ Alarm System," published November 15, 2003, ¹⁵ are only a few of the many that appeared in newspapers early after the President's announcement. Additionally, there are articles that are available examining the problems associated with BioWatch and the criticism of the project, such as a *Chicago Tribune* article published on April 6, 2003, "City's Air Monitored for Bioterror Attack: Early Detection System Criticized." ¹⁶

A more reliable source describing the program can be found through the University of Minnesota's Center for Infectious Disease Research and Policy (CIDRAP) Internet Web page, www.cidrap.umn.edu. CIDRAP is charged with providing support for the BioWatch program by assisting in defining the epidemiological planning aspects of the program as well as planning and conducting an annual BioWatch meeting for all cities that have BioWatch monitors. Therefore, CIDRAP is charged with releasing official information regarding the BioWatch Program to the public as well as preparing confidential documents related to the program.¹⁷

Documents related to events surrounding the BioWatch Program since its deployment in 2003 are primarily press releases and newspaper articles from BioWatch cities such as Houston and Washington, D.C. The research pointed to several articles

¹³ Associated Press, "Nationwide Monitoring System Planned for Detecting Bioterror Attack," January 22, 2003, http://www.fas.org/sgp/crs/terror/RL32152.html (accessed September 10, 2007).

¹⁴ Kathy Sawyer, "Biowarfare Monitors are Deployed in U.S.," *The Washington Post* (Washington, D.C.), January 23, 2003.

¹⁵ "Government Touts Germ Alarm System/'BioWatch' in Houston, 30 Other Cities," *Houston Chronicle* (Houston, TX), November 15, 2003, http://www.chron.com/CDA/archives/archive.mpl?id=2003_3708081 (accessed September 4, 2006).

¹⁶ Julie Deardorff, "City's Air Monitored for Bioterror Attack," *Chicago Tribune*, April 6, 2003, http://pqasb.pqarchiver.com/chicagotribune/access/321666171.html?dids=321666171:321 (accessed August 28, 2008).

¹⁷ Center for Infectious Disease Research and Policy, "Mission & Activities: Public Health and BioWatch," http://www.cidrap.umn.edu/cidrap/center/mission/articles/biow.html (accessed June 6, 2006).

regarding the first reported BioWatch positive "alarm" in October 2003, such as a press release on the City of Houston's official Web site, "Officials Following Up on Bacteria Detection." In addition, the Washington, D.C. BioWatch event in September 2005 also created a great deal of media coverage. "Biohazard Sensors Triggered: Mall Germ Levels Likely Not a Threat," appeared in the Washington Post on October 1, 2005 and described the event according to a press release by federal officials. ¹⁹

Government documents that provide insight to the management of the program exist through the Office of the Inspector General and through congressional record. The Office of the Inspector General released two reports 11 months apart regarding the EPA's responsibilities. Other government documents include congressional testimony, reports by the Office of Inspector General, and documents produced by DHS committees and subcommittees.

The government documents that are lacking are those that describe how the BioWatch Program management was set up and the overall vision for the program. The documents available regarding the early inception of the program are briefly mentioned in President George W. Bush's 2003 State of the Union address and some presidential directives, however, no details of the program's set up were found.

The information and documents that the author uses regarding the State of Missouri and the St. Louis BioWatch Network were obtained through meetings with partners at the federal and state levels including the; Missouri departments of Health and Senior Services, Public Safety, and Natural Resources; and, local public health and emergency response agencies. As this thesis will be public release, the author was scrupulous in maintaining confidentiality as necessary.

¹⁸ City of Houston: The Official Site for Houston, "Officials Following up on Bacteria Detection," http://www.houstontx.gov/health/NewsReleases/bacteria%20detection.html (accessed September 1, 2006).

¹⁹ Martin Weil and Susan Levine, "Biohazard Sensors Triggered: Mall Germ Levels Likely Not a Threat," *The Washington Post*, October 1, 2005, http://pqash.pqarchiver.com/washingtonpost/access/905126611.html? (accessed September 3, 2006).

II. THE BIOWATCH PROGRAM PURPOSE REVEALED FROM PAST EVENTS

A. SIGNIFICANCE BIOLOGICAL EVENTS BEFORE BIOWATCH

A goal of the BioWatch Program is the detection of a large biological weapons grade release in an outdoor or indoor situation, such as subways or postal facilities that may cause thousands of casualties. The early notification of such an attack presumably will provide a significant advantage in preventing and treating thousands of casualties, limiting illnesses and deaths by allowing earlier vaccination or pharmaceutical treatment to those exposed.²⁰ Experts, however, have questioned whether a mass biological attack is the most probable terrorist threat or if a smaller localized attack is more likely to occur negating the effectiveness of BioWatch.²¹ However, there are historical examples of a large aerosolized outdoor release, the 1979 anthrax release at Sverdlovsk (now Ekaterinburg), Russia, and an indoor release, the U.S. anthrax mailings in 2001, suggesting that such incidents are plausible and making the BioWatch Program relevant and viable tool for public health officials.

1. U.S. Anthrax Letters of 2001

The letters containing anthrax were sent through the U.S. Postal system. According to Postal Service managers, public health officials, and postal worker union representatives, the Postal Service considered the health risks to its employees ahead of its mission to deliver the mail in deciding whether to close postal facilities. The U.S. Postal Service relied on public health agencies to assess the health risks and to recommend treatment for its employees. At the time of the event, agencies involved believed risk exposure to anthrax contained in the mail to be minimal. It was not until the

²⁰ Dana A. Shea and Sara Lister, *The BioWatch Program: Detection of Bioterrorism*, Congressional Research Service Report no. RL 32152, November 19, 2003, http://www.fas.org/sgp/crs/terror/RL32152.html (accessed August 9, 2009).

²¹ Amy Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the US Response* (The Henry L. Stimson Center, Report no. 35, October 2000).

CDC confirmed cases of anthrax in postal employees at Trenton and Brentwood facilities that the seriousness of the event was realized.²² The Postal Service closed these facilities, worked closely with the CDC to provide treatment to those diagnosed with anthrax, and began prophylaxis for other employees that were in the facilities as a precautionary measure.

Local public health agencies underestimated the health risks to postal employees because they were not experienced with military grade anthrax and did not suspect that anthrax spores could leak from taped, unopened letters in sufficient quantities and cause deaths. In addition, the CDC, as well as other federal agencies, had no experience with the grade of anthrax that was contained in the letters nor had experience with the equipment that was used in the U.S. Postal Service distribution centers, equipment that "pinched" the letters and sent them through a sorting system at very high speeds. The CDC and the Postal Service have said they would have made different decisions if they had earlier understood the health risks to postal employees.²³ The decisions made early on during the anthrax letter event caused confusion, concern, and distrust in governmental officials, including public health officials at federal and state levels.

The anthrax letters of 2001 were sent through the postal system in September and October. The FBI believes that there were a total of four letters sent. Two of the letters were postmarked September 18 to the *New York* Post and to Tom Brokaw at NBC in New York. Letters to Senators Tom Daschel and Patrick Leahy were postmarked October 9.²⁴ There were confirmed human cases of anthrax at America Media in Florida and at the New York offices of CBS and ABC; however, the FBI does not believe anthrax letters were sent to these facilities, but that cross-contamination occurred from the four letters mentioned above.²⁵ Five people died from anthrax during this period of time and of the people who contracted anthrax, eleven worked for the postal service and eight for media

²² General Accounting Office, *Bioterrorism: Public Health Response to Anthrax Incidents of 2001* (GAO–04–152, October 2003), 11.

²³ Ibid.

²⁴ Council on Foreign Relations, *Backgrounder: The Anthrax Letters*, http://www.cfr.org/publication/9555/ (accessed September 16, 2009).

²⁵ Ibid.

organizations, and an infant visiting her mother at ABC News in New York also fell ill. Three other people—a bookkeeper in New Jersey, a nurse in New York City, and an elderly widow in rural Connecticut—also caught anthrax. The nurse and the widow died.²⁶

The indoor release of anthrax described above demonstrates the importance of detecting a release of a biological agent as soon as possible and the fact that a grade of anthrax that could be aerosolized that could cause illness and death was available to someone who was willing to use it with the general public. It is conceivable that if the anthrax release was detected when the letter(s) was going through the postal facility less cross contamination would have occurred, fewer individuals would have fallen ill or died, and pharmaceutical treatment of postal workers would have immediately been given assistance in saving lives and reducing illness.

2. Anthrax Release: Sverdlovsk, Russia–1979

In April and May 1979, an unusual anthrax epidemic occurred in Sverdlovsk, Russia among humans and livestock. Soviet officials at the time attributed the outbreak to consumption of contaminated meat. Articles appearing in early 1980 in Soviet Union medical, veterinary, and legal journals reported an anthrax outbreak among livestock south of the city in the spring of 1979 and stated that human cases of gastrointestinal anthrax resulted from eating contaminated meat and cutaneous anthrax cases occurred after contact with diseased animals.²⁷ In 1986, scientists from the U.S. were invited to come to Moscow for discussions with Soviet physicians who had gone to Sverdlovsk to deal with the anthrax outbreak. In 1988, two of the Soviet physicians that were a part of the 1986 discussions visited the U.S., provided formal presentations, and participated in discussions with private and U.S. government specialists. According to their account, contaminated animals and meat from an epizootic south of the city starting in late March

²⁶ Council on Foreign Relations, *Backgrounder: The Anthrax Letters*.

²⁷ Matthew Meselson, "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 266 (1994): 1202–1208.

1979 caused 96 cases of human anthrax with onsets from April 4 to May 18, 1979. Of these cases, 79 were said to be gastrointestinal and 17 cutaneous, with 64 deaths among the gastrointestinal cases and none among the cutaneous cases.²⁸

In the early 1990s, the Russian media began to release articles related to the Sverdlovsk anthrax cases. The articles included interviews with Sverdlovsk physicians who questioned the food borne explanation of the epidemic and with officials at the military microbiology facility. These officials admitted that in 1979 they had been developing an improved vaccine against anthrax but knew of no escape of the anthrax pathogen. In late 1991, Russian President Boris Yeltsin, who in 1979 was the chief Communist Party official of the Sverdlovsk region, directed his Counselor for Ecology and Health to determine the origin of the epidemic. In May 1992, Yeltsin stated that the KGB admitted that the Soviet military research regarding military grade anthrax as a biological weapon and vaccines related to the agent was related to the cause of the release.²⁹ The timeline outlines the milestones surrounding the event over a 14-year period.

- April/May 1979–Anthrax illness/deaths occur among humans and animals
- November 1979–West German, Anti-Soviet Magazine breaks the story
- June 1980–Soviet news agency TASS claimed the source of the outbreak was contaminated meat
- 1980–1990 Soviets defended story related to contaminated meat
- 1991–Sverdlovsk name changed to Ekaterinburg
- 1992–1993 U.S.-led investigation confirmed it was not a food borne outbreak

The data collected was collected in the early 1990s by U.S. scientists with assistance from Russian health officials. The sources of information were gathered from data compiled by the KGB including an administrative list giving names, birth years, and residence address of the 68 people who died, household interviews with family and friends of those who died and survivors that were designed to determine place of

²⁸ Meselson, "The Sverdlovsk Anthrax Outbreak of 1979," 1202.

²⁹ Ibid., 1202–1203.

employment and other places individuals may have been before their illness, hospital lists, clinical case histories, and other data. With this data, the researchers were able to create a plum map by plotting cases on a 1979 regional map of Sverdlovsk (see Figure 2). Scientists used case numbers for fatalities as they appeared on the administrative list. Days of onset and death are counted from April 1, 1979.³⁰

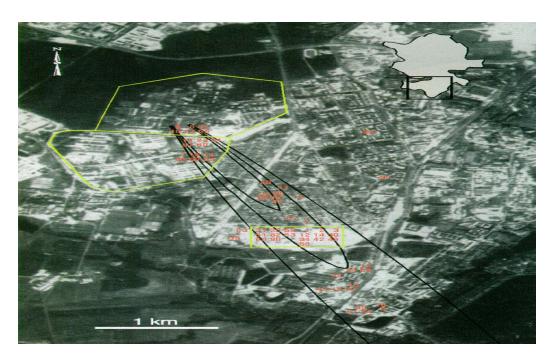


Figure 2. Sverdlovsk Plume Model.

The data from Sverdlovsk and Figure 2 are still studied today by BioWatch experts and the public health community for its application to a city such as St. Louis. The modeling and the data are critical in understanding an aerosol release of a biological agent and gives real-life data on deaths, illnesses, weather impact on aerosolized releases, and time lapse of onset of illness after the event for this particular agent. It is critical to note at this point that the BioWatch Program was created to assist federal, state, and local agencies to detect such releases as the pluming effect, demonstrated in Figure 2, immediately to save lives by providing early treatment to the population affected and information to the general public as to how to protect themselves and their families

³⁰ Meselson, "The Sverdlovsk Anthrax Outbreak of 1979," 1202–1203.

during, or immediately after, the event. The plumbing and plotting cases on the plume graph are critical in convincing officials that consequence management planning related to the BioWatch Program is important. It also supports the argument that the accountability for the planning and the day-to-day administration of the program is critical since consequence management of such a release requires strong leadership and program monitoring from the agency that provides public health policy. The Sverdlovsk case demonstrated how cases cluster as well as timing related to onset and death, giving information related to reaction time. The concern is if military grade anthrax, similar to what was mailed in the anthrax letters of 2001, can be aerosolized and dispersed over a city the size of St. Louis the Sverdlovsk, Russia data becomes significant and helps provide estimates of the casualties.

The Sverdlovsk, Russia incident and the anthrax letters in the U.S. provides evidence of several situations surrounding controversial issues among politicians, which favor silence and pretending nothing is wrong to avoid social and economic concern, public health, which favors full, early disclosure and discussions, and the general public and are especially important to the BioWatch Program including:

- Earlier detection of the anthrax release in a situation similar to that in Sverdlovsk, Russia. The BioWatch Program used with other public health tools such as syndromic surveillance can be used to determine what type of release was made within the confines of agents tested in a timelier manner so that prophylaxis can begin as early as possible. The Sverdlovsk release took place in a city of approximately 1.2 million people and there were a reported sixty-four deaths.³¹ A similar release could occur in a city such as St. Louis, which has the metropolitan statistical area (MSA) of approximately 2.8 million individual and can have a much larger impact depending on how the release was dispensed. The earlier the release is detected the more lives that can be saved.
- Public campaigns regarding the diseases that are regularly tested for can
 be developed before an event occurs so that it is ready to be released to the
 public and health care providers on a moments notice. The anthrax letters
 caused great concern among those with potential exposure and those
 coming into contact with them. Early released information campaigns can
 explain, for example, that anthrax is not transmitted from human to human
 like other agents, such as smallpox.

³¹ Meselson, "The Sverdlovsk Anthrax Outbreak of 1979," 1202–1203.

• Politicians and public health professionals may clash in cases where a release is detected. Public health professionals concern is the health and welfare of individuals and will err on the side of caution when a detection is initially occurred. Politicians, on the other hand, may be more sensitive to the economic and political ramifications of a false negative and may want to keep information concealed until more definite information is known.

3. Summary of Relevant Cases

Looking at the two incidents in tandem reveals several key issues that are a must for the BioWatch Program:

- A detection mechanism, such as the BioWatch Program, can assist public health officials and political leaders with insight and warning in large cities and indoor events of great significance, such as super bowl, political presidential conventions, subway systems, and indoor arenas that an event has occurred that is not of a natural origin.
- When biological agents are released in the air deaths and casualties will occur causing the public to look to government officials, especially public health for guidance on disease. As shown in the anthrax case, public health/CDC is the go to agency, not the EPA.

The aerosolized release in Russia provides evidence of a Soviet block biological warfare program. President Yeltsin admitted to the world that the cases in Russia were a direct result from an unintentional release of anthrax spores from a Soviet biological weapons facility. This admission alleviates any doubt that countries can and have experimented with biological weapons and leaves plenty of room for the possibility that U.S. enemies can still be producing biological military agents. Second, the fact that anthrax, or other biological agents, can be mailed and cause illness and even death through direct contact with the contaminated piece of mail as well as through crosscontamination of pieces of mail that came into contact with the contaminated letters or machinery that processed the mail. Third, biological attacks can be executed indoors as well as outdoors. Fourth, the longer a biological release is unknown the more casualties and illnesses will occur. The unknown factor can keep public health officials guessing and can lead to unclear instructions to the general public and health care officials, causing confusion and distrust of governmental officials.

The BioWatch Program was placed in the largest cities in the U.S. to assist in detecting aerosolized biological agents such as anthrax, to provide the earliest warning possible so that public health officials can start lifesaving mass prophylaxis as early as possible. In the case of the anthrax letters and the Sverdlovsk incident, the BioWatch Program could have improved the situation by alerting authorities to the release of a biological agent, hopefully prompting earlier vaccines and pharmaceutical treatment, saving lives and deterring illness. However, in order for such an early warning system to be effective, clear strategies, policies and response measures need to be in place. If they are not, the system can actually worsen the situation and degrade response because: clear messages are not available to the general public; governmental agencies will not have consistent messaging; health care agencies will be at a loss as to what to do with the influx of patients without clear public health guidance; and, as time continues, the public will distrust all information coming from governmental officials.

B. CURRENT BIOWATCH PROGRAM OVERVIEW

During the 2003 State of the Union Address, President George W. Bush announced the BioWatch Program by declaring, "We've...begun inoculating troops and first responders against smallpox, and are deploying the nation's first early warning network of sensors to detect a biological attack," emphasizing the importance of the program at the federal level and the particular interest of those in the White House.³² At this moment, there was no doubt that the BioWatch Program would be placed in U.S. cites and would be operational despite criticisms. Jacqueline Cattani, Director of the Center for Biological Defense at the University of South Florida, was quoted as saying, "It's crazy. We don't see how random air sampling can cover a large area effectively. To pick up a potential exposure to a biological agent by air monitoring or other sensor-type technology, you'd have to be extremely lucky."³³ However, in spite of the

³² "State of the Union Address," Executive Office of the President, The White House, January 28, 2003, http://www.whithouse.gov/news/releases/2003/01/20030128-19.html (accessed August 1, 2006).

³³ Mark Baard, "Bio-Whatchamacallit: Tom Ridge's 'Crazy' Plan to Watch the Sky for Spores," *The Village Voice* (March 12–18, 2003), http://www.villagevoice.com/news/0311,baard,42494,1.html (accessed August 30, 2006).

naysayers, the path to the BioWatch Program was becoming a reality before the 2003 State of the Union Address during the 2002 Winter Olympics in Salt Lake City, Utah.

During the 2002 Winter Olympics in Salt Lake City, Utah, a system called the Biological Aerosol Sentry and Information System (BASIS) was tested as a precursor to the BioWatch Program. BASIS, developed under the Chemical and Biological National Security Program of the National Nuclear Security Administration by Livermore and Los Alamos scientists, involved the placement of fifteen to twenty monitoring stations in various locations in the Salt Lake City region. The filters were collected and transported to the U.S. Department of Energy laboratory every four hours and tested for the presence of CDC's Category A Agents. Before BASIS was used in Salt Lake City, it was field tested in urban environments.³⁴ The effectiveness of BASIS is discussed later in this chapter.

Since BASIS and the 2002 Winter Olympic Games, the BioWatch Program has been established and deployed to over thirty cities across the United States. The program was developed, funded, and managed by the U.S. Department of Homeland Security's Science and Technology (S&T) Directorate and carried out in cooperation with the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) on the federal level.³⁵ BioWatch uses environmental sampling devices to detect biological pathogens quickly, such as anthrax, to assist public officials in recognizing a biological event so that lifesaving medications may be distributed to affected citizens as early as possible.

It is important to note at this point that "quickly" in the case of BioWatch Program is not immediate. The samples must be collected and taken to a laboratory where tests are runt to check for all of the agents of concern. The first Polymerase Chain Reaction (PCR) screening assay is completed soon after the sample arrives at the

³⁴ CIDRAP, "BioWatch Program Aims for Nationwide Detection of Airborne Pathogens," (February 26, 2003), http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/biowatch.html (accessed September 20, 2009).

³⁵ House Committee on Science, *An Overview of the Federal Budget R&D Budget for FY 2005*, 108th Cong., 2d sess., February 11, 2004, 67.

laboratory; normally, the testing is completed within two to six hours. If the PCR screening test is reactive, a PCR confirmatory assay must be performed on the sample, which takes another two to six hours depending on the laboratory.

The PCR positive test result is only the beginning of finding the agent's source and determining if it is a terrorist event or a naturally occurring event. The data found from the PCR positive then must be considered with other public health data that is collected on a daily basis by state and local public health department. The most important data collection and notation is from direct physician contact voicing a concern regarding a cluster of patients and a data collection system known as syndromic surveillance.

Before going further, it is important to define syndromic surveillance and its importance. Since the 2001 anthrax attacks, "syndromic surveillance" has many definitions. For the purposes of this paper, the CDC definition of "syndromic surveillance" will be used: syndromic surveillance is constant surveillance using healthrelated data that precede diagnosis and signal a sufficient probability of a case or an outbreak to warrant further public health response. Although, historically, syndromic surveillance has been utilized to target investigation of potential cases, its utility for detecting outbreaks associated with bioterrorism is increasingly being explored by public Syndromic surveillance is distinguished from other methods of health officials. surveillance by the data types monitored as potential indicators of a disease or outbreak. For the purpose of detecting bioterrorism, indicators are nonspecific expressions of the target diseases that occur before a diagnosis would routinely be made. These indicators may include absenteeism from work or school, purchases of over-the-counter health products such as facial tissues, orange juice, allergy medicine and cold medicines, laboratory test requests, or visits to a health-care facility with, for example, symptoms indicating upper respiratory infection.³⁶

The data described above must be identified, grouped, and analyzed in such a way that is logical and provides the best information to public health professionals as possible.

³⁶ Daniel M. Sosin, "Syndromic Surveillance: The Case for Skillful Investment," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 4 (Winter 2003): 247.

This step in the syndromic surveillance process is critical and must be done with care and quickly in order for early intervention to occur. A timeline must be developed that includes exposure, symptom onset, health behavior, health care encounter, medical evaluation, initial findings, and final diagnosis, for example. The problem with syndromic surveillance is that it is useless on its own unless there is intelligence regarding an attack, which BioWatch can assist in confirming. The BioWatch filters that may present a positive can be coupled with syndromic surveillance that will include patients that may present early to physicians with symptoms because of weakened immune systems. Without BioWatch information, there is no way to know that an attack has occurred until individuals show signs and symptoms in large clusters. In the treatment of many agents of concern, when symptoms appear the survival rate is lowered considerably. Table 1 describes the CDC's Category A agents' public health impact and resistance to medical treatment.

Biological Agent	Public Health Impact	Resistance to Medical Treatment
Pneumonic Plague (Yersinia pestis)	Pneumonic Plague causes fever, headache, weakness, and rapidly developing pneumonia with shortness of breath, chest pain, and cough. The pneumonia progresses for 2 to 4 days and may cause respiratory failure and shock. Without early treatment, 90% of the patients die.	Plague can often be treated with antibiotics, but only if given within the first 24 hours.

Biological Agent	Public Health Impact	Resistance to Medical Treatment
Anthrax (Bacillus anthracis)	Anthrax has a 1–7 day incubation period. Onset of severe symptoms occurs within 2–5 days of incubation. Hospitalization is often required for those showing disease symptoms. Unvaccinated, untreated individuals with inhalation anthrax suffer up to 90% fatalities. ³⁷	Anthrax responds well to antibiotic therapy. The recover rate is 70 percent if antibiotic treatment is started early.
Tularemia (Francisella tularensis)	Tularemia causes respiratory failure, shock and death. The mortality rate of tularemia without antibiotics treatment has been as high as 30%–60%. With treatment, the fatality rate falls to 2%.	Tularemia is treated with antibiotics.
Smallpox (Variola major)	Smallpox is recognizable by a widespread, full body rash. If treated smallpox has a greater than 30% fatality rate among unvaccinated populations.	Vaccine given within 72 hours of exposure reduces disease severity. There is no other treatment for smallpox. It is important to note that smallpox was eradicated before antivirals and other modern medicines were invented. The data on hand is only from before 1975.

³⁷ Note: This number is based on what is known from data before the fall of 2001 anthrax letters. It is possible with new treatment and hospital care the rate may be lower, however, there is no significant data to support the assumption.

Biological Agent	Public Health Impact	Resistance to Medical Treatment
Clostridium botulinum toxins	Ingestion of botulinum toxin causes difficulty speaking, seeing and/or swallowing, leading to increasing paralysis that may include respiratory paralysis. Recover from paralysis can take from weeks to months. Inhalation of botulinum toxin causes more rapid onset of symptoms.	Exposure to botulium toxin can be treated with antitoxin. This treatment stops further damage, but does not reverse current paralysis. Mechanical breathing assistance and supportive care are required in acute cases.
Hemorrhagic fevers	There are many types of hemorrhagic fevers including, Machupo, Bolivia, Ebola and Marburg. Symptoms for hemorrhagic fevers range from fever, headache, sore throat, diarrhea, internal and external bleeding, shock, and liver failure. The fatality rates range from 50%–90% for Ebola to 5%–30% for Machupo.	For most hemorrhagic fevers, there is no specific treatment. Only supportive care can be provided.

Table 1. Biological Agent Characteristics³⁸

The BioWatch Program is designed to be a component of daily public health surveillance to complement and refine syndromic surveillance that some states, Missouri being one, are now doing electronically. The detection of a covert act of bioterrorism, unless detected by the BioWatch Program, is likely to occur only through syndromic surveillance or an astute physician. The BioWatch Program adds another system that can provide evidence that a release has occurred, making available an additional tool to public health in order to alert health providers on the ground with specific instructions

³⁸ Dana A. Shea and Frank Gottron, CRS Report for Congress, *Small-scale Terrorist Attacks Using Chemical and Biological Agents: An Assessment Framework and Preliminary Comparisons*, May 20, 2004, 65–76.

before a patient has presented with signs and symptoms. Thus, detection is delayed from the time the event occurs to when individuals develop signs and symptoms. Therefore, even though "fast" is a qualified statement, since BioWatch takes time for lab processing, it is still much faster than the alternative.

Figure 3 gives a pictorial of the importance of the timeline when detecting a biological event. Note that the "Biological Sensors" will detect the event before syndromic surveillance begins to see clustering of symptoms. In order to make the public health detection system work more effectively, public health officials at the state and local levels must be intimately involved in the BioWatch planning and leadership efforts and have rapid access to BioWatch findings.

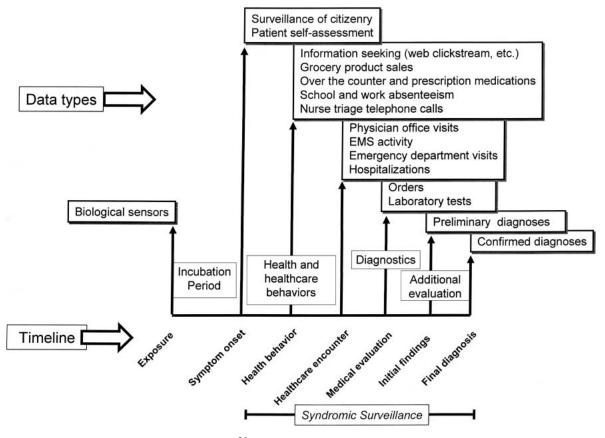


Figure 3. Disease Intervention.³⁹

³⁹ Kenneth Mandl et al., "Implementing Syndromic Surveillance: A Practical Guide Informed by the Early Experience," *Journal of the American Medical Informatics Association* 11 (March/April 2004): 143.

Despite its difficult beginnings, the BioWatch Program has gained public and Congressional interest for several reasons, including its relevance to syndromic surveillance, the possibility of early detection of disease, its high price tag, and the promise of future development of sensors that transmit readings to laboratories without the tedious collection of filters and indoor systems with alarms that can alert individuals immediately when a biological agent has been detected. The reasons for congressional interest listed above directly translate into increases in the Homeland Security Research and Development (R&D) budget. BioWatch is responsible for the majority of a 15 percent increase in Homeland Security R&D at the Department of Homeland Security. The 2005 Homeland Security R&D budget received approximately a \$104 million increase from fiscal year 2004. The entire increase was directed toward biological countermeasure activities, including the expansion of BioWatch coverage in highly populated cities and piloting an integrated warning and assessment system for biological attacks.⁴⁰

The currently-deployed BioWatch Program, known as Phase I, detects six of the top threats from the CDC's A and B lists, some of which are listed in Table 2. This includes anthrax, tularemia, and smallpox. To date, not all the agents that BioWatch tests for have been made public. Advanced detection systems, now under development, will increase the number detected. It is believed that the program will reasonably detect more than twenty high-threat agents, including markers for antibiotic resistant and engineered organisms by 2009.⁴¹ The ultimate goal is to have the BioWatch sensors deployed so that eighty percent of the U.S. population will be living in areas monitored by the equipment.⁴²

While serving the primary function of mitigating attacks, the BioWatch Program as well as other detection programs, plays a significant role in deterrence. Logically, terrorist may be less likely to attack when they know that defensive systems prevent them

⁴⁰ House Committee on Science, An Overview of the Federal R&D Budget for Fiscal Year 2005, 9.

⁴¹ Ibid., 154.

⁴² CIDRAP, "BioWatch Program Aims for Nationwide Detection of Airborne Pathogens."

from attaining their goals.⁴³ Thus, the BioWatch Program and the advancement of its technology are unlikely to be discontinued. Therefore, it is vital to assess the entire program and make changes, as needed, to improve the program in order to make it more efficient and practical in the future.

The information in this section shows the value of public health's input and continuous monitoring of the BioWatch Program. The state and local public health agencies are designed to work together to provide surveillance and disease planning and therefore should work together and answer to each other for this program as much as any other program that is disease related.

Debate among public health and scientists since the deployment of BioWatch included the ability of the sensors to pick up naturally occurring bacterium. In addition, if the sensor did pick up naturally occurring bacterium how would officials and laboratory officials distinguish between natural and manmade. Additionally, how will officials know when to announce the BioWatch positive to the public? Moreover, if announced to the public and it is only a naturally occurring event, how will the public react to the unnecessary panic caused?

C. HISTORY OF BIOWATCH ALARMS SINCE PLACED IN U.S. CITIES

1. Salt Lake City, Utah–2002 Winter Olympics

During the 2002 Winter Olympic Games, one PCR positive caused some concern through an ambient air program that was deployed for the Olympic Games and before BioWatch was placed in U.S. cities. On February 12, 2002, a sample collected at the airport was positive on more than one single-strand test. The airport was alerted by officials and was warned that they may need to evacuate. However, before the final decision to evacuate, airport officials decided to wait on follow-up testing, which consequently showed that the organism was a nonpathogenic organism.⁴⁴

⁴³ House Committee on Science, An Overview of the Federal Budget R&D Budget for FY 2005, 56.

⁴⁴ CIDRAP, "BioWatch Program Aims for Nationwide Detection of Airborne Pathogens."

While awaiting the results of the confirmatory testing, the airport started preparing to close and hazardous-materials teams were suiting up for possible duty. There are no open sources that indicate that consequence management and mass prophylaxis plans were in place in case a positive sample was detected. Evidence has shown that public health was involved with the incident since Scott Williams, the Deputy Director of the Utah Department of Health, was the spokesperson for the potential positive; however, he did not have a lead role in the event nor was contacted early on in the event. Williams also noted that there was no preparation for the air monitoring system through tabletop exercises or other scenarios that were executed before the Olympics.⁴⁵ Thus, it is reasonable to deduce that Olympic security partners were not as prepared as needed for a biological release. Additionally, from the information that is available in public sources, it appears that partners may have not taken the possibility of a biological attack seriously since tabletop scenarios did not address a positive BioWatch filter and it was not discussed with public health officials before the Olympics.

2. Houston, Texas

The first incident of a positive BioWatch result after the program was deployed in U.S. cities was reported on October 9, 2003 in Houston, Texas. The Houston Department of Health and Human Services reported detecting low levels of the bacterium that causes tularemia, *Francisella tularensis*. According to a media release, positive results were detected on three consecutive days, October 4, 5, and 6, 2003, with negative results on subsequent days. The response to the positive result was a modest one: Precautionary measures were taken by the local and state public health agencies, including increased surveillance for human illness; additional environmental sampling and testing; and assessment of activities in the area that may have caused the sensors to pick up the organism. There were no signs that the presence of the bacterium resulted from an intentional release; rather, it was naturally occurring.

⁴⁵ CIDRAP, "BioWatch Program Aims for Nationwide Detection of Airborne Pathogens."

⁴⁶ CIDRAP, "Signs of Tularemia Agent Detected in Houston Air," (October 10, 2003), http://cidrap.umn.edu/cidrap.content/bt/tularemia/news/oct1003 (accessed September 4, 2006).

⁴⁷ Ibid.

The city of Houston began syndromic surveillance for signs and symptoms of tularemia while follow-up collection of filters and testing of those filters and collection and testing of rabbits and rodents, which are natural carriers of tularemia, were being completed. There were no human cases of tularemia that were found during the time period in question, after a three- to five-day incubation period.⁴⁸

Health officials were involved with media releases and messaging to the public. The City of Houston's news release reported, "Precautionary measures being taken by the City of Houston's Health and Human Services Department and Harris County Public Health and Environmental Services include increased surveillance for human illness, additional environmental sampling, collection and testing of wild rabbits and rodents and an assessment of activities in the area that may have caused the sensors to pick up the organism."⁴⁹

What we do not know from the newspaper articles and other open documents are the interactions between state and local officials and state EPA departments and the state and city public health departments. Those items have been discussed in closed sessions and are not available for unlimited publication.

The October 2003 BioWatch positive was closely monitored by all BioWatch cities since it was the first positive alarm to occur. Many were doubtful that the BioWatch sensors would actually do what they were designed to do. Other public heath officials were concerned that the sensors would read positive much of the time because many of the agents being tested are naturally occurring and would cause unnecessary concern and panic. The Houston positive samples were the sentinel events that public health, environmental professionals, and governmental officials were waiting for since the BioWatch Program was released to the original cities after the 2002 Winter Olympic Games.

⁴⁸ CIDRAP, "Signs of Tularemia Agent Detected in Houston Air."

⁴⁹ City of Houston: The Official Site for Houston, "Officials Following up on Bacteria Detection."

3. Washington, DC

The Centers for Disease Control and Prevention notified the states of Maryland and Virginia and the District of Columbia on September 30, 2005, that an airborne form of tularemia bacterium was detected by six air sensors in the National Capitol Mall area during the weekend of September 24–25, 2006.⁵⁰ A week after the detection of the tularemia bacterium, there were no signs of illness that would result from the exposure and the event was determined to be most likely occurring naturally in the environment.⁵¹

The activities surrounding the Washington, D.C. event unfortunately exposed gaps between systems and partners in the BioWatch Network in the nation's capitol, and was discussed openly in the media. Public health officials were not notified for five days that BioWatch had a positive alarm in the Mall. According to media reports, the U.S. Department of Homeland Security delayed alerting the Centers for Disease Control and Prevention because subsequent tests were not conclusive.⁵² As a result, state and local public health officials were not alerted and no planning actions were taken to ensure that anti-war rally participants at the Mall during the time of the positive samples, as well as tourists that visit the area on a daily basis, were notified. This incident gave health care professionals serious pause and concern. Public health professionals began to question how countless individuals that may eventually scatter across the U.S. and the world would be notified of a possible biological release and where to go for disease investigation and treatment. This example demonstrates that the lack of consistent reporting mandates between agencies is inefficient for the BioWatch Program and may cause delay in saving lives at the local level. The need for a leadership role of the state and local health departments in the BioWatch Program is evident from this example.

⁵⁰ Weil and Levine, "Biohazard Sensors Triggered: Mall Germ Levels Likely not a Threat."

⁵¹ Petula Dvorak, "Health Officials Vigilant for Illness After Sensors find Biohazard on Mall," *The Washington Post*, http://pquasb.pqarchiver.com/washingtonpost/access/905365901.html? (accessed October 2, 2005).

⁵² Susan Levine and Sari Horwitz, "Test Results Cited in Delay of Mall Alert," *The Washington Post*, October 5, 2005, http://pquasb.pqarchiver.com/washingtonpost/access/906716421.html (accessed September 3, 2006).

4. St. Louis, Missouri

A routine BioWatch detected *F. Tularensis* in St. Louis, Missouri. The positive filter was collected on October 17, 2006 near Busch Stadium. However, follow-up tests on subsequent filters found no evidence of the bacteria that causes tularemia.⁵³

This particular positive result, however, may have caused concern among public health officials because of the location of the filter. In October 2006, the St. Louis Cardinals played in the National Baseball League Playoffs on October 14, 15, and 17, and in the World Series on October 24, 25, and 27 in Busch Stadium in downtown St. Louis. There is no open source to determine how or if the fact the National Baseball Playoffs or the 2006 World Series being played in Busch Stadium had an impact on the response efforts to the BioWatch positive. However, the news media did report to the location of the sensor that provided the positive sample, which is not protocol for the BioWatch program and against protocols of the Missouri Department of Health and Senior Services,. The *St. Louis Post Dispatch* reported, "A routine test of air quality near Busch Stadium on Monday turned up traces of a rare and potentially fatal bacteria that federal officials have warned could be used by terrorists as a biological weapon." Therefore, knowing where the positive was discovered would lead one to believe that there was considerable concern for the playoff games.

It is unknown how the information regarding the location of the sensor leaked, however, it was not in the Missouri Department of Health's media release and no local public health agency had knowledge of the mention of the sensor site. The leak, however, emphasized some issues related to the BioWatch Program and the misunderstandings and lack of communication between partners at the federal, state, and local levels and emphasizes the importance of how BioWatch Program reporting and leadership must have a strong definition and policies. The leadership developed and policies must be followed by all involved in order for leaks such as this that can complicate matters with response and consequence management.

⁵³ Metro Digest, "Air-quality Test Finds Rare Bacteria," *St. Louis Post-Dispatch*, October 18, 2006 http://stltoday.com/help/archives/simplesearch, (accessed August 14, 2009).

⁵⁴ Ibid.

In addition to the sensor, location leak the BioWatch positive for *F. Tularensis* was met with several other challenges. The Missouri BioWatch Program had several issues that many other BioWatch cities have faced according to the U.S. Department of Homeland Security's Office of Inspector General report "DHS' Management of BioWatch Program. The report describes several issues plaguing BioWatch Programs in the report.

- Improper transfer of exposed filters
- Improper decontamination of the Chain-of-Custody bags, inner bags, and holders
- Procedural errors made in the handoff from the field personnel to the laboratory personnel
- Improper quality control⁵⁵

In addition, there was confusion between state departments and the role that each would take during the Missouri BioWatch process. The entity assigned to transporting samples that were collected outside of normal collection times was not aware of all their responsibilities. The Department of Natural Resources (DNR), Missouri's department that is similar to the U.S. EPA was responsible for the day-to-day collection of samples, but did not completely understand their role in collections taken outside normal collection times and was not able to get clear guidance from the U.S. DHS. The local public health agencies had not exercised using extra collection kits provided by DNR and were unfamiliar with procedures.

Despite the many things that needed improvement, some things did go well for Missouri. The notification calls of the BioWatch Advisory Committee were completed in a timely manner and a conference call with federal, state, and local officials was successful, the extra samples were taken and made their way to the Missouri State Public Health Laboratory for testing, and federal, state, and local officials agreed on the who would be the spokesperson for the event, and decisions were made quickly and effectively.⁵⁶

⁵⁵ DHS' Management of the BioWatch Program, 5.

⁵⁶ This information is from personal notes from the author.

In summary of the numbered items above, the BioWatch Program has had several problems to overcome and still has many with which to deal. The cities above that have had BioWatch positive results on a filter have struggled with issues similar to Missouri's. In each of the examples, it is evident that public health agencies are anxious to take on a role in the BioWatch Program and want to ensure planning is in place and that the planning efforts are appropriate through exercises and multi-discipline partnerships. Issues that are relative to all of the BioWatch cities and continue to be areas of concern between EPA and public health programs are the following.

- Location of sensors and if the best locations have been selected for the purpose of BioWatch
- What are the guidelines of collecting samples when there has been a positive sensor? How do we protect those that are collecting the samples to determine if there is a wide spread release without alarming the general public? For example, do the sample collectors go out in full gear depending on the agent or do they continue to collect samples without gear until a confirmation?
- At what point is the general public, health care professionals, and hospital staff notified of the potential release?
- How and who is to fund the planning and exercise efforts for the BioWatch Program when there is limited funding for equipment and supplies, which is provided to the laboratories?
- How does the public health preparedness efforts dovetail into BioWatch planning and exercises? What role does the Cities Readiness Initiative, Strategic National Stockpile, and the Hospital Preparedness Program in the BioWatch Program and how to ensure the programs support each other.

These and other questions and problems are still prominent in BioWatch cites and burden planning processes.

D. PROGRAM IMPLEMENTATION ANALYSIS-PUBLIC HEALTH NATIONAL TRENDS IN THE BIOWATCH PROGRAM

Since the program began in 33 cities across the U.S. in 2002, there have been five national meetings: 2003, 2005, 2006, 2007, and 2008. In addition, the DHS is contracting with CIDRAP to host and plan regional meetings so that cities may work

together on a more intimate basis to share information, strategies, policies, and lessons learned over the past year. It is through the general information of these meetings and the facts that they bring that analysis has occurred for this subject.

The BioWatch Program's first national meeting was in 2003 and there is no data from this session available for the analysis. The program was very new at that time and many individuals involved are no longer involved.

The DHS has provided national meetings for BioWatch participants for five years. As indicated above information regarding attendants is not available for the first program and for the 2007 and 2008 meetings are not available due to lack of the availability of a participant list, however, details of the second and third national meetings are in Table 2. Table 2 clearly shows the numbers and percentages of attendance by profession. In 2005 and 2006, participation by the state health departments was 19 and 16 percent more respectively than the state EPA departments. In addition, local public health provided 13 percent more than its EPA counterpart in 2005 and 24 percent more in 2006. Nationally, the data shows that the BioWatch Program has a significant affect on public health at the state and local levels, however, there is no responsibility or accountability required of the state health agency in the process. However, the state and local public health departments are struggling to take leadership as needed but have no authority to do so at the state and local levels.

PARTICIPANT GROUP	2005 BIOWATCH NATIONAL MEETING- NUMBER ATTENDING	~ % OF TOTAL	2006 BIOWATCH NATIONAL MEETING- NUMBER ATTENDING	~ % OF TOTAL
State Health Department	91	24%	89	21%
Local Health Agency	68	18%	120	29%
U.S. EPA	46	12%	40	10%
State EPA Department	17	5%	20	5%
Local EPA Agency	19	5%	23	5%
Other (Law enforcement, contractors, emergency response, etc.)	137	36%	123	30%
TOTAL	378		415	

Table 2. 2005 and 2006 National Meeting Attendees

In addition to the National BioWatch meetings, the DHS BioWatch Program has contracted with CIDRAP to provide regional programs. The participant representation from the 2007 regional programs is listed in Table 3. The data is presented here as aggregate data in order to maintain sensitive information related to the BioWatch Program.⁵⁷ This data reflects the data from the national meetings. A majority of the attendees, 33 percent, are from state health departments followed closely by local public

⁵⁷ The data described in Table 4 was calculated from the Meeting Participant List provided by CIDRAP for each of the regional meetings. The names of the individuals are not available for the general public due to sensitive issues related to the BioWatch Program. The data in Table 4 is also missing data from two regional meetings because the meetings had not taken place or the Meeting Participant List was not available to the author. However, it is unlikely that the participant lists from these meetings would show significant differences in the professions attending the meetings.

health agencies at 31 percent. The federal, state, and local EPA participant groups came in at 3 percent each, showing again that the primary interest and planning efforts are with the state and local public health agencies.

PARTICIPANT GROUP	2007 REGIONAL BIOWATCH NATIONAL MEETING- NUMBER ATTENDING	~ % OF TOTAL
State Health Department	130	33%
Local Health Agency	122	31%
U.S. EPA	10	3%
State EPA Department	13	3%
Local EPA Agency	11	3%
Other (Law enforcement, contractors, emergency response, etc.)	107	27%
TOTAL	393	

Table 3. 2007 Regional Meeting Attendees

In addition to the participants, the agendas for the BioWatch Regional meetings are reflective of the BioWatch Program and the fields of interest related to the program. Appendix C is a sample of an agenda from one of the regional meetings that were held in 2007. From the opening remarks to the panel discussions, public health staff dominates. In this sample, which is typical of the other agendas for the 2007 regional meetings, speakers include state and local public health agency staff for lessons learned from actionable results to facilitated discussions for regional planning, which also include local fire, police, Federal Bureau of Investigations, and mass transit, and input from federal, state, and local EPA. The sample agenda indicates that the role of federal, state, and local EPA is mechanical in collecting and replacing filters, assisting in filter placement in the cities, assuring that filters and sample collecting are consistent and uncompromised, and management of that area of the program. The federal, state, and local EPA are not

responsible, however, for the consequence management and assurance of the public health response of the program when a positive filter is indicated. That is the responsibility of the federal, state, and local public health agencies.

This evidence does not mean that the federal, state, and local EPA does not have a role in BioWatch, but it does indicate that their solo leadership role should be eliminated and instead shared with public health at the state and local levels as well as the federal level. EPA is vital to the measurement process and the technical side of the BioWatch program. However, in order for BioWatch to achieve its full potential, it needs to be the mandate and the responsibility of the people who will ultimately use and respond to the information–public health.

E. RELATIONSHIP OF BIOWATCH WITH PUBLIC HEALTH

As mentioned earlier in this paper, there are governmental reports indicating that the U.S. EPA struggles with the administration of the BioWatch Program. Reports include the March 23, 2005 Office of Inspector General's reports, "EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program" and the February 20, 2004 report, "EPA's Homeland Security Role to Protect Air From Terrorist Threats Needs to be Better Defined." The reports argue that the U.S. EPA does not have a framework in place to carry out the program and need guidelines for state and local entities to follow to improve quality assurance. The BioWatch program's primary purpose it to ensure safe air; however, it is testing for biological agents that will harm and cause a need for treatment for a large population within a very short period of time, depending on the agent within forty-eight hours. The response to the findings will need to be carried out by public health at the local, state, and federal levels.

Given the information in the two documents above, this thesis argues that the U.S. EPA, although it has a role, is not the appropriate agency to provide guidance to the public health community for BioWatch in regards to disease surveillance, planning and strategies. Currently, the EPA programs at the federal and state levels are being asked to set mandates and regulations for planning efforts for agencies with whom federal and state EPA programs do not have a traditional relationship nor does the state or federal

EPA programs know how to plan for biological events that threaten the health and lives of the general public. Currently, the state and federal EPAs are expected to provide structure and make judgments related to filter placement, safety of those collecting filters, and the urgency of information dissemination to critical partners. To fix the problem of the struggles of the federal and state EPAs, a new approach is needed so that the state public health departments can take the administrative responsibilities over the local public health agencies, which is obviously a strong relationship.

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III. SOLUTIONS

As mentioned in the Introduction, the BioWatch Program is a new program in the civilian world and there is little data at this point to analyze. However, there have been several positive hits, including one in St. Louis during the major events of the 2006 National League Playoffs and the World Series, and several management meetings where implementation strategies were discussed. Given that this is a new program, there are improvements and changes being made yearly and policies and procedures are being evaluated. However, one constant is that the U.S. EPA is the lead agency at the federal level, receiving dollars from the U.S. DHS, and the state EPAs are the lead at the state level. There are two solutions that this thesis will explore to provide public health the muscle they need to gain more control of the program and provide needed guidance to public health agencies for program administration.

A. RESTRUCTURING AT THE FEDERAL LEVEL

The first considerations for the federal BioWatch Program is restructuring the program at the federal level or at least consider how the program is presented to all agencies involved in order to establish new leadership or provide guidance on a shared leadership between two federal agencies and clearly defined roles for sister agencies at the state and local levels. The restructuring would take a great deal of work and commitment from the federal departments and would require the CDC to either take those that now administer the program into their agency or take the administrative duties and place those duties on existing staff or add new staff. In addition, the CDC would have to provide the U.S. EPA with their portion of the dollars for equipment and supplies related to the BioWatch Program and develop procedures for reporting between the agencies. The CDC also should be inclusive of the BioWatch Program in the Public Health Preparedness Cooperative Agreement. Although the state agencies can plan and provide funding for exercises related to the BioWatch Program, there is no supporting

language in the guidance that outlines expectations of the states with BioWatch Programs and does not require states with BioWatch Programs to address how the program is being supported and planning efforts related to the program.

B. DEVELOPMENT OF MOAS AT THE STATE LEVEL

An alternative to restructuring at the federal level would be to pursue individual, state level memorandum of agreement (MOA) between the state departments of EPA and public health to create an agreement between the agencies that will make the BioWatch Program implementation and monitoring solid and will move the program forward in states and cities that are struggling. The second solution shifts the changes to the state level where each state can control the split between the agencies and each can provide their own unique language to the solution. To make this work, the state agencies must develop a MOA and clearly define which agency has what role and administrative duties.

A possible guide for how these MOA can be established is the MOA entered into by the US EPA and the CDC in 2004 titled: "Memorandum of Agreement Among the Department of Homeland Security, the Centers for Disease Control and Prevention, and the Environmental Protection Agency," Appendix B. Although conversation regarding this MOA was discussed earlier in this paper, the content and basic ideas behind the MOA are relevant and should not be dismissed and can be applied to other MOAs developed for the purpose of BioWatch. The MOA provides details for the two agencies and outlines the responsibilities of each including the following.

- Services provided by the CDC to the EPA and state and local agencies
- Services provided by the EPA to the CDC and local U.S. EPA programs
- CDC and U.S. EPA performance standards
- U.S. DHS responsibilities
- Regular reports
- Meeting schedule
- Points of contact in each program

Using this structure, the state agencies can enter into agreements that focus on the problems and needs unique to the state BioWatch Program. Through research and by

partnering with key individuals at the state, EPA the author suggested that a MOA be developed that would outline clearly the role of the state health department as well as the responsibilities of each state department. Appendix D is a sample MOU that the state of Missouri developed during the author's employment there to make the BioWatch Program stronger and functional. The Missouri MOA includes the following.

- Establishment of administrative responsibilities to the state department of health related to the local public health agencies
- Establishes an annual BioWatch exercise through public health funding
- Establishes meeting timelines between the state health department and the state EPA department
- Defines the role of the state EPA to the U.S. DHS and the reporting requirements

The MOA will change the make up of the BioWatch Program at the state level and eventually the local level by providing the state health department with authority to mandate the local public health agencies to exercise the BioWatch Program and have developed policies and procedures for such things as defining what agency(ies) will be responsible for picking up samples outside the normal pick up time if warranted by a positive, attending mandated meetings set by the state EPA and health departments related to the BioWatch Program, and requiring consequence management policies.

A new implementation process would be provided by introducing the MOA as seen in Figure 4. The MOA would strengthen the state public health's role in the process and would allow the entity to provide invaluable administrative oversight that is lacking in the BioWatch Program. Currently, the state EPA does not have the ability to demand that local public health agencies attend mandatory meetings where critical decisions are made, nor do the local public health agencies have a regular schedule for BioWatch Program exercises because the state EPA does not have funding sources for them to support the exercises. The new implementation plan would also provide dollars to the program through the Public Health Preparedness Cooperative Agreement by planning exercises and training around the BioWatch Program that fit into the goals of the Cooperative Agreement. The MOA opens a new avenue for strategies and policies that are lacking in the program as described above.

Figure 4 demonstrates how the MOAs would support the BioWatch Program among the primary partners. The U.S. Department of Homeland Security, the U.S. Environmental Protection Agency, and the Centers for Disease Control and Prevention would continue to work with their MOA and strengthen the ties among the agencies. In a mirror of that MOA, the state agencies that reflect their federal partners would develop an MOA that echo their own needs and strengthen their relationship and process related to the BioWatch Program.

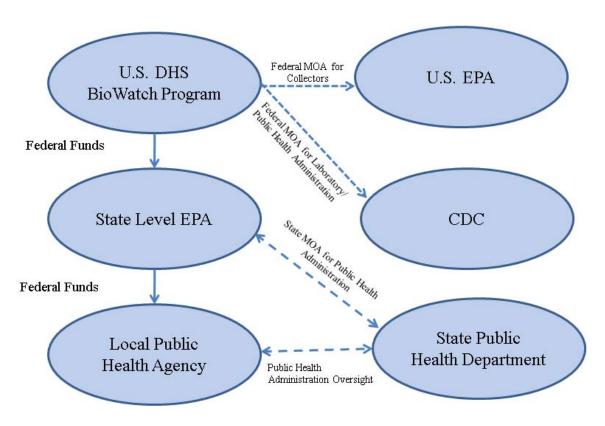


Figure 4. Proposed BioWatch MOA Implementation

IV. CONCLUSION

A. PROS AND CONS OF SOLUTIONS

The solutions above have both hurdles that must be overcome for implementation. The first solution of moving the program at the federal level is, though not impossible, may be a bit impractical. The expense of moving the program from the U.S. EPA to the CDC can be expensive and cause further confusion at the state and local levels. It is also evident that both the CDC and the U.S. EPA share aspects of the program and neither seem to have the edge over the other when it comes to a clear leadership role. This particular solution also may not solve the most pressing implementation and response problems of BioWatch.

Both the EPA and the CDC need to have leadership roles within BioWatch. Having sole leadership with the EPA has generated many problems as documented in this thesis. However, having sole leadership with the CDC may also lead to problems. The BioWarch program does not work without the air quality control expertise of the EPA. It is those individuals that run the program day to day by overseeing collection of the samples, ensuring appropriate equipment and supplies are on hand and provide technical training to individuals who collect daily samples. Therefore, shifting the program to the CDC for primary responsibility may simply reverse the leadership problems at the state and local levels.

The second option is more viable and responsible. It would provide the following.

• The ability of the states to develop their own MOAs and divide leadership roles for their own situation. For example, Missouri may also want to have some type of MOA with public health agencies or the EPA program in Illinois because the program is a bi-state program, which comes with its own complications.

- A simple solution to a complex problem that can be solved without involvement from the federal level.
- A written guide for expectations for each of the programs that have the primary responsibility of keeping the BioWatch Program working on a day to day basis and the entity that must know what to do when the "bell rings."

It must be noted, however, that the MOA solution is not the answer to all problems. As in the example of the federal MOA, it only is a solution if the signees follow the guidelines and if they provide the services and products, they have agreed.

The implementation of the MOA for the state of Missouri was a challenging effort. Both departments are required to go through legal review and agreement must be realized before the MOA can be put into place, which takes valuable time. In addition, the MOA does not transfer any dollars for the monitoring and administration of the BioWatch Program in relationship to the local public health agencies. In times where dollars are limited, the MOA is difficult to support by management because dollars for other efforts must be used to carryout the objectives of the MOA. Moreover, there has to be someone within each department that has to take a special interest in making the MOA a living document; without that component, the MOA fails to provide the shift in policy required.

B. PROBLEMS FOR FURTHER RESEARCH

Further research is urgently needed into the problems and options for the BioWatch Program and leadership issues. The research and findings should include "For Official Use Only" documents such as after action reports, surveys and interviews with BioWatch leaders with the understanding that the findings will be only for limited distribution. The real findings and strengths to this argument is in those materials and interviews. Until those findings can be discovered, compiled, and considered, other solutions and considerations cannot be compared to the solutions outlined in this paper.

APPENDIX A.

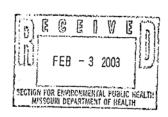
DEPARTMENT OF NATURAL RESOURCES

www.dur.state.mo.us

JAN 30 2003

Col. Tim Daniel
Director
Office of Homeland Security
P.O. Box 809, Truman Building Room 760
Jefferson City, MO 65102

Dear Col. Daniel:



On January 9, 2003, staff from the Missouri Department of Natural Resources participated in a conference call about using existing ambient air stations around the country to perform monitoring for biological agents such as anthrax spores. Agencies on the call were asked to coordinate with their state Homeland Security offices and state health departments. The department has already contacted DOHSS and notifying you by this letter.

The call was initiated by Ralph Marquez, from the Environmental Council of the States, who advised states that Governor Tom Ridge, Director of the Department of Homeland Security, would soon be sending a request to the governors of various states to solicit their participation in air monitoring in conjunction with the U.S. Environmental Protection Agency (EPA). The call covered operation and deployment of the monitoring network, the instruments to be used, laboratory analyses, and funding.

Apparently, the Department of Homeland Security would like to deploy a network of air monitors used for measurement of particles smaller than 10 microns (PM10) within the next 60 days. The proposed network would include daily sampling with 5-10 PM10 monitors at existing monitoring sites in 20 of the major cities in the nation. According to Jeff Holmstead, the EPA representative on the call, the cities have not been chosen yet. But based on the fact that Missouri was invited to participate in the call and the general discussion, St. Louis and Kansas City could reasonably be expected to be among the cities where monitoring is conducted.

Filters from the samplers would be collected on a daily basis and sent to laboratories approved by the Center for Disease Control (CDC) for analysis. A network of labs included in the National Response Laboratory Network will probably be used. The only biological agent named on the call was anthrax, though it may be possible to detect other agents that produce spores. However, viruses, such as small pox, and chemical agents would not be able to be detected.

Integrity and excellence in all we do

C)

Col. Tim Daniel Page Two

The Department of Defense already has \$40 million appropriated for this network. According to EPA, the funds would be distributed to the states through a separate grant and would not affect any other funds received from EPA. The funds would cover equipment purchase if necessary, installation of monitoring equipment, and maintenance. The funding for laboratory analysis was not addressed specifically though staff assumed it would come from the same source.

The main benefit of the monitoring seems to be to give hospitals earlier warning about the release of anthrax or certain other biological agents. However, based on the information provided in the call, it is not clear that this proposal provides a technical solution likely to be effective. Specifically, staff question the likelihood of detecting any biological agents with only 5-10 outdoor samplers in a large metropolitan area. In addition, the turn around time for laboratory analysis would have to be extremely short in order to provide much notice for public health officials. Other concerns relate to whether mailing filters to a lab is viable, the amount of staff that will be needed for 365 day monitoring, the amount of training needed to safely handle filters, and whether this could eventually become an unfunded federal mandate.

The need to be prepared for homeland defense is clear to all of us. However, we need to be sure that what we do is based on sound science and is meaningful. We will advise you as soon as we obtain further information. States were advised that another call on this subject will be held soon. In the meantime, if you have questions, please contact Jim Werner at 751-0763 or Earl Pabst at 526-3344. Thank you.

Sincerely,

DEPARTMENT OF NATURAL RESOURCES

Stephen Mahfood

Director

SM:cks

c: Gale Carlson, DOHSS

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APPENDIX B.

Memorandum of Agreement

Execution Copy

MEMORANDUM OF AGREEMENT AMONG THE DEPARTMENT OF HOMELAND SECURITY THE CENTERS FOR DISEASE CONTROL AND PREVENTION AND THE ENVIRONMENTAL PROTECTION AGENCY

THIS MEMORANDUM OF AGREEMENT ("MOA") is hereby entered into on March 5, 2004 (the "Effective Date") among the Department of Homeland Security ("DHS"), the Centers for Disease Control and Prevention ("CDC"), and the Environmental Protection Agency ("EPA"), hereinafter jointly referred to as the "Parties" and individually as a "Party".

1. BACKGROUND AND PURPOSE

- 1.1 BACKGROUND. The DHS Directorate of Science and Technology has established a Chemical, Biological, Radiological, and Nuclear Countermeasures program to prepare for and respond to a wide range of terrorist threats involving weapons of mass destruction. As part of this effort, DHS is partnering with CDC and EPA to implement and administer a program involving the deployment of a network of sensors to detect and report the release of bioterrorist pathogens in densely populated areas ("BloWatch"). BioWatch is an early warning system that is designed to detect trace amounts of biological materials in the air rapidly, whether they result from intentional release or constitute minute quantities that might occur naturally in the environment. BioWatch will assist public health experts in determining the presence and geographic extent of a biological agent release, allowing Federal, state, and local officials to determine emergency response, medical care, and consequence management needs more quickly.
- 1.2. PURPOSE. The purpose of this MOA is to set forth the terms and conditions by which: (a) CDC and EPA will provide services and technical expertise to BlöWatch; (b) the Parties will coordinate and manage their respective responsibilities for BloWatch; and (o) DHS will provide DHS Funds (ás defined in Section 4 below) and management oversight to CDC and EPA. The Parties agree that they will review this MOA if the BloWatch program expands or otherwise changes gipnificantly as compared with its configuration as of the Effective Date and, if necessary, effect appropriate amendments hereto.

2. AUTHORITY

This MOA is entered into pursuant to the Economy Act of 1932, as amended (31 U.S.C. 1535), Sections 302(2), (4), (5)(B), and (13) of the Homeland Security Act of 2002 (Public Law 107-296), and Section 103(b)(2) of the Clean Air Act, as amended (42 U.S.C. 7401 et seq.). In accordance with FAR 17.503, the following Determination and

DHS' Management of BioWatch Program

Findings ("D&F") have been made: (a) use of an interagency acquisition for services is in the best interest of the Government; (b) the supplies and services rendered by CDC and EPA pursuant to this MOA cannot be obtained by DHS as conveniently or economically by contracting directly with a private source; and (c) in CDC's and EPA's capacity as servicing agencies under this MOA, CDC and EPA are authorized by law to purchases supplies or services on behalf of DHS if such purchases are necessary to fulfill their obligations under this MOA and the attached unclease. agreement.

3.1. DESCRIPTION OF SERVICES.

3.1.1 SERVICES PROVIDED BY CDC. CDC and its Laboratory Response Notwork (*LRN*) will provide technical expertise and services to BloWatch, including but not limited to: (a) laboratory analysis services; (b) developing and implementing specific protocols for each laboratory comprising the LRN and designated as a laboratory responsible for BloWatch filter testing; (e) coordinating laboratory analyses with state health departments and state public health faboratories; (d) coordinating activities with EPA; (e) tasking DOE National Laboratories (through DHS) to provide external filter analysis and consulting services on a contingency basis; (f) providing leadership technical assistance to state and local health departments regarding the management of public health emergencies resulting from the BloWatch program's detection of biological pathogens; (g) preparing and issuing situation reports as necessary, and (h) such other services as are directed by DHS in connection with BloWatch and described in a funds transfer document issued pursuant to Section 5 below (collectively, "CDC Services.") CDC will only use DHS Funds for CDC Services. For clarification, CDC may also use DHS Funds for the following activities, materials, supplies, and personnel related to BloWatch: laboratory stating; redurning supplies; diagnostic hardware; critical and specialty regents; training; testing; fravel directly related to the BloWatch program; and personnel evaluation. CDC may only utilize DHS Funds for other purposes (even if such purposes are related to BloWatch) upon the written authorization of the DHS BloWatch Program Manager.

3.1.2 SERVICES PROVIDED BY EPA. EPA will provide services and technical expertise to BioWatch including but not limited to: (a) establishing, deploying, operating, and maintaining a network of sensors (the "BioWatch Sampling Network") in the BioWatch Cities (as defined in Section 3.2 below); (b) establishing, operating, and maintaining a filter collection process (in accordance with mutually agreed EPA Performance Standards as described below) for such BioWatch Sampling Network; (c) coordinating the monitoring activities of the BioWatch Sampling Network with state and local environmental monitoring agencies; (d) coordinating activities with CDC; and (e) such other services as are directed by DHS in connection with BioWatch and described in a funds transfer document issued pursuant to Section 5 below (collectively, "EPA Services"). EPA will only use DHS Funds for EPA Services. For clarification, EPA may use DHS Funds for the following activities, materials; supplies, and personnel related to BioWatch: program staffing; recurring supplies and equipment; hardware and software

DHS' Management of BioWatch Program

used to track samples, site monitors, or complete programs directly related to BioWatch; training; testing; travel directly related to the BioWatch program; and personnel evaluation. EPA may only utilize DHS Funds for other purposes (even if such purposes are related to BioWatch) upon the written authorization of the DHS BioWatch Program Manager.

3.2 BIOWATCH CITIES. As of the Effective Date of this MOA, DHS has provided to EPA and CDC a first of cities which will be monitored as part of BioWatch (BioWatch Cities). The designation of cities as BioWatch Cities is sensitive but unclassified information which may not be disclosed to the public. The Parties agree that during the course of this MOA and upon written notice to CDC and EPA, DHS may designate additional cities, different cities, or fewer cities as BioWatch Cities.

3.3 PERFORMANCE STANDARDS.

3.3.1 CDC PERFORMANCE STÁNDÁRDS. CDC will perform the CDC Services in accordance with the following performance standards: (a) adhering to CDC-established criteria for public health reference laboratories; (b) adhering to all BloWatch standard operating procedures and protocols contained in the "Standard Operating Procedure Manual" developed by the Parties; and (c) adhering to such other standards as may be mutually agreed by the Parties (collectively, the "CDC Performance Standards").

3.3.2 EPA PERFORMANCE STANDARDS. EPA will perform the EPA Services in accordance with the following performance standards: (a) adhering to all BloWatch standard operating procedures and protocols contained in the "Standard Operating Procedure Manual" developed by the Parties; (b) coordinating with CPC to ensure that each filter within the BloWatch Sampling Network arrives at the designated LRN facility or atternate facility (i.e., LLNL or atternate sign) in a finely manner in order to facilitate timely analysis of the filters by CPC in partnership with state public health laboratories; and (c) adhering to such other standards as may be mutually agreed by the Parties (collectively, the "EPA Performance Standards").

4. DHS RESPONSIBILITIES

DHS will provide funding to CDC and EPA in accordance with DHS's appropriations and available funds ("DHS Funds") and in accordance with the number of BloWatch Citles. DHS will also provide strategic management oversight to CDC and EPA for the services and technical expertise CDC and EPA will provide to BloWatch. DHS will provide a full-time BloWatch Program Manager to provide overall feadership for BloWatch, including budgeting and assigning tasks to CDC and EPA. The BloWatch Program Manager will also brief CDC and EPA periodically on upcoming changes to the BloWatch program (e.g., expansion of the program's scope). DHS will also provide an Operations Director who will oversee and direct day-to-day DHS operations of BloWatch. As of the date of this MOA, the BloWatch Program Manager is to be determined by DHS, and the Operations Director is Mr. Brian M. Hayes. DHS may

DHS' Management of BioWatch Program

replace such designees at any time upon notice to CDC and EPA. If there is a national emergency or elevation of the national threat level, DHS may provide EPA and CDC with verbal instructions for operational changes (e.g., monitoring additional cities or increasing the frequency of testing filters from the BioWatch Sampling Network) and, at a later date, provide written notice of such operational changes.

Certain Department of Energy ("DOE") National Laboratories, particularly Los Alamos and Lawrence Livermore National Laboratories, will provide technical expertise in biological sampling systems and training assistance to state and local agencies as determined by DHS in accordance with its arrangements with DOE.

5. FUNDING

5.1 PAYMENT OF FUNDS.

- 5.1.1 PAYMENT OF FUNDS TO CDC. DHS will provide, through Interagency funds transfers, DHS Funds to CDC for the CDC Services. DHS Funds will be allocated by CDC for laboratory staffing, recurring costs (e.g., reagents and expendables), travel, administration, and information technology support for the thencurrent fiscal year. If the number of BioWatch Cities is expanded, DHS will allocate additional DHS Funds (if available) to CDC for the additional CDC Services.
- 5.1.2 PAYMENT OF FUNDS TO THE EPA. DHS will provide, through an Interagency funds transfer, DHS Funds to EPA for the EPA Services. DHS Funds will be allocated by EPA for program staffing, recurring costs (e.g., supplies and equipment), travel, administration, and information technology support for the thencurrent fiscal year. If the number of BioWatch Cities is expanded, DHS will allocate additional DHS Funds (if available) to EPA for the additional EPA Services.
- 5.2 REMBURSEMENT OF EXCESS COSTS AND EXPENSES. From time to time, DHS may increase the National Alert Status based on threats to national security. When DHS increases the National Alert Status, both CDC and EPA will create situational reports that identify the total number of personnel hours and amount of materials used in connection with the CDC Services and the EPA Services beyond normal operating parameters and submit such reports to DHS upon the lowering of the National Alert Status or upon DHS's request. DHS will subsequently provide additional DHS Funds to EPA and CDC as reasonably necessary to reimburse EPA and CDC for additional CDC Services and EPA Services beyond normal operating parameters.
- 6.3 REIMBURSEMENT OF EXCESS PAYMENTS TO DHS. EPA and CDC will carry over unobligated DHS Funds into the new fiscal year and subtract the balance from their budget requests for additional DHS Funds. Upon termination of BioWatch, EPA and CDC will promptly return all unobligated DHS Funds to DHS.

DHS' Management of BioWatch Program

REPORTS AND MEETINGS

REPORTS.

6.1.1 CDC REPORTS. CDC will provide an operations and expense report for each laboratory within the LRN where CDC Services are performed (with each report containing the following cost categories: laboratory staffing; recurring costs (e.g., reagents and expendables); travel; administration; information technology support; and a numeric breakdown of monthly laboratory costs as a factor of per filter analysis). CDC will provide such operations and expense reports to DHS on a monthly basis by the fifth day of each month containing information partaining to the preceding month. CDC will also provide the following categories or reports to DHS on a quarterly basis by the fifth day of each quarter containing information related to the previous quarter so that DHS may monitor the performance of the CDC Services; (a) problem and problem resolution reports (e.g., problems encountered with the CDC Services, root cause analysis, and problem resolution efforts); (b) CDC Performance Standards reports (meeting of CDC Performance Standards and failure to meet CDC Performance Standards); and (c) such other reports as may be reasonably requested by DHS.

8.1.2 EPA REPORTS. EPA will provide an operations and expense report for the BioWatch Sampling Network (with each report containing the following cost categories: staffing; recurring costs (e.g., supplies and equipment); travel; administration; information technology support; and a numeric breakdown of monthly costs on a per BioWatch City basis). EPA will also provide the following categories of reports to DHS on a quarterly basis by the fifth day of each month containing information pertaining to the preceding month. EPA will also provide the following categories of reports to DHS on a quarterly basis by the fifth day of each month containing information pertaining to the preceding month. EPA will also provide the following categories of reports to DHS on a quarterly basis by the fifth day of each month containing information related to the previous quarter so that DHS may moni

6.2

- 6.2.1 MEETINGS WITH CDC: Meetings among CDC, associated public health partners, and DHS will be held at either Party's request and upon reasonable notice.
- 6.2.2 MEETINGS WITH EPA. Meetings between EPA and DHS will be held at either Party's request and upon reasonable notice.
- 6.2.3 STEERING COMMITTEE MEETINGS. DHS will conduct bi-weekly steering committee meetings among DHS, EPA, and CDC representatives to manage coordination of BioWatch. Steering committee members will include operational leads from EPA, CDC, and DHS. The steering committee will be chaired by the DHS

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BioWatch Program Manager. In the meetings, committee members will give status reports, discuss operational issues, and discuss any potential future changes to the BioWatch program. Minutes from the steering committee meetings will be available for each Party's review. Steering committee meetings may be held more frequently upon DHS's request.

7. PROJECT MANAGEMENT .

7.1 POINTS OF CONTACT.

7.1.1 DHS FOINTS OF CONTACT. The primary point of contact at DHS with regard to issues related to BloWatch (other than day-to-day operations) will be the DHS-designated BloWatch Program Manager. The Operations Director, Mr. Brian M. Hayes of DHS will be the point of contact for day-to-day operations of BloWatch.

Operations Director:
Mr. Brian M. Hayes
Directorate of Science and Technology
Department of Homeland Security
Washington, DC 20528
Phone: 202-772-9700
Fex: 202-772-9745
Mobile: 202-360-3165

7.1.2 CDC POINTS OF CONTACT.

Strategic Lead:
Dr. William Raub
Principal Deputy Assistant Secretary
Office of the Assistant Secretary for Public Health Emergency Preparedness
Départment of Health and Human Services
Phone: 202-205-2882

Charles A. Schable Director Office of Terrorism Preparedness & Emergency Response Centers for Disease Control and Prevention 404-639-7405

Day-to-Day management:
Dr. Michael Miller.
Bloterroriem Proparedness and Response Program
National Center of Infectious Diseases
Centers for Disease Control and Prevention
Phone: 404-639-3029

DHS' Management of BioWatch Program

Charles Schable Blotemorism Preparedness and Response Program National Center of Infectious Diseases Centers for Disease Control and Prevention Phone: 404-639-3996

7.1.3 EPA POINTS OF CONTACT.

Mr. Nealson Watkins
U.S. EPA, Office of Air Quality Planning and Standards
Monitoring & Quality Assurance Group (C339-02)
Research Triangle Park, NC 27711
Phone: 919-541-5522
E-mall: Watkins.nealson@epa.goy
Fax: 919-541-1903

- 7.2 INTERAGENCY COORDINATION. The BloWatch Program Manager will coordinate with EPA and CDC representatives to track daily activities associated with BloWatch. EPA and CDC will execute daily operations and tasks associated with BloWatch to maintain functionality of the EPA services and CDC Services to ensure continued and uninterrupted BloWatch operations. EPA and CDC will promptly report known, anticipated, or recurring problems with BloWatch operations to the BloWatch Program Manager to ensure continuity of BloWatch operations.
- 7.3 DISPUTE RESOLUTION. The BioWatch Program Manager will coordinate dispute resolution activities among the Parties. If the dispute is at the operational level, the DHS Operations Director will intervene and resolve as appropriate.
- 7.4 RECORD RETENTION. Records related to the CDC Services and EPA Services will be retained by CDC and EPA, respectively, as directed by the BioWatch Program Manager in writing (e.g., record type epd length of time to be held). EPA will retain field eampling records from the BioWatch Sampling Network for one (1) year, unless otherwise directed by the BioWatch Program Manager.

SECURITY POLICIES .8.

Except documentation cleared for public release through DHS public affairs, the Parties will label all documentation related to BloWatch "For Official Use Only" and such documentation will be subject to release and destruction requirements associated with such labeling, which shall be provided to CDC and EPA by the BloWatch Program Manager in writing.

DHS' Management of BioWatch Program

9. AMENDMENT

The terms of this MOA may be modified in writing upon the mutual agreement of the Parties.

10. TERM AND TERMINATION

10.1 TERM. The term of this MOA shall begin on the Effective Date and shall expire one (1) year after the Effective Date (the "Initial Term"). The initial Term shall automatically renew for successive one-year renewal terms, unless DHS provides written notice to EPA and CDC at least skty (60) days prior to the expiration date of the then-current one-year term of its intent not to renew this MOA, in which case this MOA will terminate as of the expiration of then then-current term.

10.2. TERMINATION. Each Party may terminate this MOA for convenience and without cause at any time by giving the other Parties at least sixty (60) days prior written notice (with copies to the General Counsel's Office of each Party) designating the termination date.

APPROVED and AGREED BY:	
Department of Homeland Security Name: FRANTHANT VECKSTRANT Title: School and Technicold Veckstrant of technicold Veckstrant Date: Macual S. Sook	Fil Centers for Disease Control and Prevention Names Property Analysis Secretary Title: Criticist Dearly Analysis Secretary Date: 02 Angland Control Control
Province Protection Agency Name: Title: Assola at Adm Date: Aug. 7, 200 fa	DHS Warranted Contracting Officer Name:

DHS' Management of BioWatch Program

APPENDIX C.

Draft Agenda

7:00 REGISTRATION

8:00 WELCOME AND OPENING REMARKS

Al Romanosky (Moderator)

Office of Public Health Preparedness & Response Maryland Department of Health and Mental Hygiene

Michael Osterholm, Director

Center for Infectious Disease Research and Policy (CIDRAP)

Jeffrey Stiefel, Director, Early Warning Division

Department of Homeland Security, Office of Health Affairs

8:35 BIOWATCH PORTAL

Brian Maguire, Communications Outreach Manager Global Secure Systems

8:45 BIOWATCH MULTIPLEXED PCR ASSAY (BIO-PLEX)

Richard Meyer, Senior Advisor to the Director Division of Bioterrorism Preparedness and Response Centers for Disease Control and Prevention

9:30 GUARDIAN PROGRAM BRIEFING

Lt Col Karen House, United States Air Force Director, CBRN Installation Protection Program

10:00 BREAK

10:20 OUTDOOR ENVIRONMENTAL SAMPLING

Moderator: Robert Myers, Deputy Director Scientific Programs Maryland Department of Health and Mental Hygiene Laboratories

Outdoor Guidance Document Overview
CAPT Ken Martinez, Associate Director
NIOSH-Emergency Response & Preparedness Office
Centers for Disease Control and Prevention

Development of Play Books and Response Plans,

Phase I and II

Don McLaughlin, Federal On-Scene Coordinator, E.P.A. Region III United States Environmental Protection Agency

Gyspy Moth Study W. Brent Daniel Los Alamos National Laboratory

11:40 LESSONS LEARNED FROM A BIOWATCH ACTIONABLE RESULT

St. Louis BioWatch Program

Nancy Bush, Director, Center for Emergency Response and Terrorism Missouri Department of Health and Senior Services

12:00 LUNCH (on your own)

1:30 INDOOR ENVIRONMENTAL SAMPLING

Moderator: Al Romanosky, Office of Public Health Preparedness & Response Maryland Department of Health and Mental Hygiene

Indoor Sampling Issues and Practical Applications
Mark Durno, Federal On-Scene Coordinator, E.P.A. Region V
United States Environmental Protection Agency

Indoor Sampling Playbook Development
William Hoppes, Environmental Scientist
Chemical and Biological National Security Program
Lawrence Livermore National Laboratory

Approaches for Indoor Environmental Sampling Response Planning CAPT Ken Martinez, Associate Director NIOSH-Emergency Response & Preparedness Office Centers for Disease Control and Prevention

2:30 BREAK

2:50 PANEL: INDOOR PROGRAM

Moderator: Michael Osterholm, Director

Center for Infectious Disease Research and Policy

DHS Programmatic Issues, Placement of Indoor System, Awareness Building TBD (Jeff Stiefel)

NCR System Perspective, Metro System
Lt. George W. Burns, Counter Terrorism Coordinator
Washington Metropolitan Area Transportation Authority

New York Regional Response Plan
David Dlugolenski, Manager, Disaster Mitigation
Office of Emergency Management
The Port Authority of New York and New Jersey

4:00 RISK COMMUNICATION

Federal Perspective

Chad Wood, Risk Communications Advisor

Department of Homeland Security, Office of Public Affairs

Local Perspective
TBD

4:25 WRAP UP

4:30 ADJOURN

APPENDIX D.

DRAFT SPECIAL PURPOSE MONITORING NETWORK MEMORANDUM OF AGREEMENT

Between

Missouri Department of Natural Resources

And

Missouri Department of Health and Senior Services

1.0 Background and Purpose

- 1.1 BACKGROUND: The U.S. Department of Homeland Security provides funding to the Missouri Department of Natural Resources to administer the BioWatch Program in the City of St. Louis. The program administration consists of contracting the local public health agencies to collect and replace filters and to provide training and education to those that will be providing filter collection on a day-to-day basis and during times of positive results on filters.
- 1.2 PURPOSE: The purpose of the MOA is to set forth the terms and conditions by which the Missouri Department of Health and Senior Services will provide monitoring of the local public health agencies to ensure administrative duties, including training and consequence management planning efforts, are completed and reported to the Missouri Departments of Natural Resources and the Missouri Department of Health and Senior Services so that timely and accurate reporting can be made to the U.S. Department of Homeland Security.

2.0 Definitions

- 2.1 <u>Department of Health and Senior Services</u>: Referred to as "DHSS" herein.
- 2.2 <u>Missouri Department of Natural Resources</u>: Referred to as "DNR" herein.
- 2.3 <u>Special Purpose Monitoring</u>: Referred to as "SPM" herein.
- 2.4 U.S. Department of Homeland Security: Referred to as "DHS" herein.

3.0 Deliverables

- 3.1 DHSS shall provide training, education, and supply provide a BioWatch exercise support through the City Readiness Initiative (CRI) for the St. Louis CRI Region annually. DHSS and DNR will participate in the exercise as support to the local public health agencies.
- 3.2 DHSS shall perform the monitoring of the DHS St. Louis area Special Purpose Monitoring Network subgrants to ensure that administrative duties are completed that relate to training and education. DHSS will monitor the subgrantees attendance at all mandated meetings, training, and education as required by DHSS, DNR, and DHS.
- 3.3 DHSS shall review local planning documents related to the BioWatch Program and shall provided feedback as needed. DHSS staff that review the planning documents shall have at a minimum a "secret" clearance.
- 3.4 DHSS shall report the monitoring findings identified in 3.1 above to the DNR. Upon notification of non-compliance, DNR agrees to collaborate with DHSS to withhold the appropriate amount of funding until the subgrantee's administrative obligations have been fulfilled.
- 3.5 DHSS and DNR agree to meet twice annually to discuss program management.
- 3.6 DHSS will provide assistance to DNR in the development of the subgrants language pertaining to the administrative duties as identified in 3.1 above in compliance with the Centers for Disease Control and Prevention and the DHS.
- 3.7 DHSS will provide assistance to DNR in the development of grant applications as they relate to 3.1 above.
- 3.8 DHSS will sign the attached DHS Non-Disclosure agreement. DNR will provide DHSS with grant language pertaining to the security requirements in which DHSS agrees to abide.

4.0 Termination

This agreement shall become effective upon the signature of all parties and shall remain in effect until otherwise agreed upon by the parties. All parties may modify the terms of this agreement upon the consent and signature of all.

5.0 Capacity to Enter Into Agreement

The persons executing this Memorandum of Agreement on behalf of DNR and DHSS/Center for Emergency Response and Terrorism hereby represent and warrant that they have the right, power, legal capacity, and appropriate authority to enter into this agreement on behalf of the entity for which they sign.

Missouri Department of Health	Missouri Department of
and Senior Services	Natural Resources
XXXXXX, Director	XXXXXX, Director
XXXXXX, Director	XXXXXX, Director
Center for Emergency Response & Terrorism	Air Pollution Control Program
XXXXXX, Division Director	XXXXXX, Division Director
Division of Community and Public Health	Division of Environmental Quality

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